SUPPORTING STATEMENT FOR SUBSTANCES APPROVED FOR USE IN THE PREPARATION OF MEAT AND POULTRY PRODUCTS

A. Justification

1. Necessity for the Information Collection

Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires FDA to evaluate the safety and regulate the use of food additives in or on all foods; section 721 provides FDA with comparable authority over color additives. The Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 601(m)(2) and 21 U.S.C. 453(g)(2)) authorize the administrator of FSIS, USDA to determine the suitability and regulate the use of ingredients in or on meat and poultry products in federally inspected facilities.

Because the two agencies regulate meat and poultry products under different statutory mandates, the FDA regulations that govern the use of food and color additives and generally recognized as safe (GRAS) substances include conditions, formats, and terms that are not fully consistent with USDA=s. Under the current process, firms producing meat and poultry products submit separate petitions to each agency. The two agencies then conduct separate, sequential reviews with each applying its respective procedures to ascertain that a substance is safe (FDA) and suitable (USDA) for the use intended in or on meat or poultry products. The regulatory change related to this OMB submission allows the customary petition information necessary to FDA and USDA reviews be combined in one petition so that separate reviews can be conducted simultaneously.

Current FDA regulations require that a petition to use a food or color additive be submitted in triplicate. The regulatory change of this OMB submission amends regulations in 21 CFR ∋ 71.1(c), ∋ 170.35(c) and ∋ 171.1(c) to require a firm to submit one additional copy of its petition when the firm states the substance is intended for use in the production of meat and poultry products.

Attached are copies of the appropriate sections of FDA=s statute and regulations mandating or authorizing the collection of information.

2. Uses of the Information

Under the FFDCA, FDA evaluates the safety of substances added to all food, including the addition to meat and poultry, and approves the intended use of food and color additives. The laws that the FSIS administers may preclude the use of a substance in meat or poultry products for reasons of efficacy and suitability. The requirement of an extra copy of the petition allows streamlining the two agency approval process by sending

the fourth copy to FSIS so that it can conduct its review concurrently.

3. Use of Improved Information Technology

Currently, there is no reporting requirement to collect petition information through the use of automated, electronic, mechanical, or other technological collection techniques. FDA does not object to receiving submissions electronically.

4. Efforts to avoid duplication

The purpose of changes to FDA regulations regarding the submission of petitions for the use of food ingredients and sources of radiation is to accommodate a simultaneous review with FSIS. The coordination of petition requirements of the two agencies reflects an interagency effort to ease the burden on regulated industries and consumers. Such coordination streamlines the federal government=s food ingredient approval process and affirms a commitment to the goals for the Reinventing Food Regulations part of the President=s National Performance Review. The coordination of petition requirements entails no new information collection beyond that previously submitted to both agencies and does not require a separate submission to the FSIS.

5. Methods to Minimize Burden on Small Businesses

This rule will benefit the regulated industry including small businesses through the elimination of duplicative approval processes that exist now allowing that only one petition be submitted to the FDA for the entire Federal government and facilitate a more timely introduction of safe food additives, color additives and other substances lawfully used in meat and poultry products.

6. Consequences to Federal Program if Collection of Data Less Frequent.

Data collection cannot be less than one time. Petitioners initiate the request for a safety review and are required to supply data for the review at that time.

7. Special Circumstances

This rule requires a firm to submit four copies of its petition when the firm states the substance is intended for use in the production of meat and poultry products. A new substance for general food use or a new use for a previously listed substance to be reviewed by FDA requires that the firm be explicit that its request is intended for use in meat and poultry products and be accompanied by appropriate data.

8. Proposal soliciting comments on the regulation

The December 29, 1995 (60 FR 67490), proposed rule provided a general comment period that closed on March 14, 1996, and reopened for another 60 days ending June 3, 1996. However, because of an oversight, FDA did not specifically solicit comments on the information collection provisions of the proposed rule, as required by the PRA. Therefore, FDA is providing an opportunity for public comment under the PRA at this time. This final rule will solicit comments under the Paperwork Reduction Act 1995. In the same issue of the FR (60 FR 67490), FDA proposed cooresponding changes to its regulations on the submission of petitions for the use of food ingredients to accommodate a simultaneous review by the two agencies. Comments received to the proposal all generally supported FDA=s proposal but added specific comments on issues of regulatory authority, policy, and procedures that both agencies should use to harmonize the review of petitions to authorize the use of substances in meat and poultry products.

In accordance with 5 CFR 1320.8(d), on Friday, August 25, 2000, (65 FR 51758), a 60-day notice for public comment was published in the Federal Register. No comments were received from the public

9. Payments or Gifts

No payment or gifts are given to respondents.

10. Confidentiality

The confidentiality of certain food ingredient information provided in petitions may be considered trade secret and is restricted from public disclosure. This is clarified in the two regulations, §§ 71.1 and 171.1. This final rule requires that petitioners soliciting an FDA review and approval of safety to use a substance in meat and poultry products be aware that a suitability review by FSIS is also required by law. Petitioners are, therefore, requested to be explicit about the intended use of the additive and the approval to release their submission to the other agency for simultaneous review.

11. Sensitive Questions

The information collection does not involve any questions of a sensitive nature.

12. Estimate of Burden

FDA estimates the burden for this collection of information as follows:

Estimated Annual Increase in Reporting Hour Burden[1]					
21 CFR Section	No. Of Respondents	Annual Frequency of Response	Total Annual Responses	Increase in Hours per Response	Total Increase in Hours
71.1 and 171.1	10	1	10	2	20

[1]There are no capital costs and or maintenance costs associated with this collection of information.

FDA estimates during a year that among the petitions on a substance requiring a safety review and intended for use in foods, ten of those petitions will include use of the substance in meat and poultry products. Submission of a petition for a substance and its use in meat and poultry products is a one time event. The FDA estimates that the respondent would expend two hours to make a fourth photocopy of the petition, necessary for FDA to send to FSIS to conduct a simultaneous review. FDA, therefore, estimates the total burden hours for data collection of the fourth copy of ten petitions intended for use of a substance in meat and poultry products to be 20 hours per year.

Cost to the Respondent:

The estimated total increase in annual time burden was twenty hours. This estimate reflected burden imposed by 10 petitions in the year. Using an estimated average of $50.00 per hour for employee time in the preparation of the fourth copy of a petition, the two additional hours of time burden for each petition would cost a respondent approximately $100.00. Materials ((250 sheets + toner) x .20 per page) would cost approximately $50.00. Total costs to the respondent for the fourth copy of each petition is estimated to be $150.00 or less.

13. Other Costs to the Respondent

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to the Federal Government

There are no significant costs to the FDA for transfering the extra copy of the petition to FSIS for its simultaneous review and for making a few phone calls during the respective

reviewing processes to coordinate completion times.

15. Changes or Adjustments in Burden

This is a new collection.

16. Statistical Analysis, Publication Plans, and Schedule

Information obtained from this data collection will not be published.

17. Approval Not to Display Expiration Dates

No approval not to display expiration date requested.

18. Exception to Certification Statement

No exceptions requested.

B. Collections of Information Employing Statistical Methods

This collection of information does not use require or use any statistical methods.